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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/445,297	12/02/1999	ROGER PETRUS GEREBERN VANDECRUYS	JAB-1282	9783

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EXAMINER

WARE, TODD

ART UNIT PAPER NUMBER

1615

DATE MAILED: 05/07/2002

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/445,297

Applicant(s)

VANDECRUYS, ROGER PETRUS
GEREBERN

Examiner

Todd D Ware

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 March 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2,4-15 and 20-22 is/are pending in the application.
- 4a) Of the above claim(s) 21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2,4-15,20 and 22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Receipt of request for extension of time (granted) and preliminary amendment both filed 3-6-02 is acknowledged.

Continued Prosecution Application

1. The request filed on 3-6-02 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/445,297 is acceptable and a CPA has been established. An action on the CPA follows.

Election/Restrictions

2. Claim 21 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 4.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 2, 4-15, 20, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over De Sousa Goucha Jorge (EP 0 689 844; hereafter '844).

'844 teaches poorly water soluble active agent compositions comprising, a cyclodextrin, a water soluble acid, and a water soluble organic polymer wherein the amounts of these ingredients are within the instant ranges (abstract; page 2, lines 25-43; page 3, lines 4-14; example 7; claims). '844 does not specifically teach or disclose that the physical state of the composition is a glass thermoplastic phase nor that the release profile of the composition is the same as that of the instant claim. However, '844 does teach that the tablets of example 7 are in a matrix as prepared according to example 5. This example states that the ingredients are kneaded in a slurry for 30 minutes and that the resulting paste is dried under reduced pressure. Kneading the composition would mix the ingredients into a homogenous/uniform system. Therefore, it appears '844 meets this limitation. Regarding the release profile of '844, a release profile for example 7 in water at 37° C is provided and shows that at 60 minutes, between 48.4% and 32.7% drug is release depending on the amount of Methocel K4MP (less drug is released with increased amount of methocel). It is stressed that the release profile of example 7 is provided for dissolution in water and the instant claims require a particular release profile in 0.1N HCl. The Patent Office is not equipped to manufacture products put before it and then obtain prior art products and make physical comparisons therewith. Therefore, the burden is shifted to the applicant to demonstrate that the composition of '844 does not have the instant release profile. In the event that the release profile for '844 is not the same as the instant claims, it is submitted that '844 also teaches that the polymer is rate controlling and extends the release of the formulation. Therefore, it would have been obvious to one skilled in the art at the time

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of the invention to decrease the amount of methocel to increase the dissolution of the composition –the motivation to provide a faster release composition of the agent.

Response to Arguments

5. Applicant's arguments filed 3-6-02 have been fully considered but they are not persuasive. Applicant argues that there is no teaching in '844 to motivate one of ordinary skill in the art to make the instant claimed composition. In response, it is submitted that no evidence demonstrating that the release profile of '844 is different from the instant release profile has been provided. It is also submitted that '844 teaches extending the release of the active agent through increase of methocel. Accordingly, it would have been obvious to one skilled in the art at the time of the invention to provide a faster release by decreasing the amount of methocel in the formulation where the motivation is to achieve a faster release formulation of the active agent.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Todd D Ware whose telephone number is (703) 305-1700. The examiner can normally be reached on M-F, 8:30 AM - 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703)308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703)

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308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

tw
May 5, 2002

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600